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RECALL OF DEFECTIVE MEDICAL DEVICES AND MEDICAL PRODUCTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy on recalls involving medical devices and medical products. ***NOTE:** For the purpose of this Directive, the Food and Drug Administration (FDA) definition of medical device is used (see subpar. 2d(5); and medical products include: drugs, subsistence (food and food service products), implantable devices, including human tissue, and prosthetics.*

2. BACKGROUND

a. The FDA has statutory authority to prescribe a recall and to rule on the extent and scope of the recall for medical devices, infant formula, and human biological products which present a risk of injury, gross deception, or are otherwise defective. FDA does not have the same statutory authority over other products, including drugs, foods, cosmetics, or supplements; however, it does have oversight responsibilities to ensure that appropriate recall actions are taken when necessary to protect the public's safety. When a product is determined to be potentially hazardous, FDA has a responsibility to monitor so that the appropriate level of voluntary manufacturer action is taken to notify all users of the product and to provide instructions for its removal or recall if necessary. If a manufacturer does not take the appropriate voluntary action that FDA believes is necessary, the Agency may seek legal action under the Food, Drug and Cosmetics Act to achieve the desired corrective action(s).

b. VHA Recall Notices, Patient Safety Alerts, and Patient Safety Advisories may be used to notify Department of Veterans Affairs (VA) users about risks associated with drugs, subsistence items, medical devices, medical products, or human tissue.

(1) Patient Safety Alerts disseminate urgent notices that require immediate, specific action on the part of the recipient to address actual or potential threats to the life or health of VA patients and staff.

(2) Patient Safety Advisories are issued when a potential threat due to equipment design, product failure, procedural issues, or training has been identified; actions are more general in nature; and implementation may be subject to local judgment contingent on local conditions.

(3) Recalls are issued to notify the field of unsafe or defective medical devices, medical products, drugs, subsistence (food and food service products), implantable devices (including human tissue), or prosthetic products that present an actual or potential threat to health or life and must be corrected and/or removed from service or use. In some cases recalls may be generated through development and dissemination of a Patient Safety Alert or Patient Safety Advisory.

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c. The information leading to the decision to issue a recall may originate from a wide variety of internal and external sources, including safety and quality management reporting systems, Safe Medical Device Act reports, manufacturers, other Federal agencies (e.g., FDA), or external organizations (e.g., Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Institute for Safe Medication Practices (ISMP), ECRI (formerly known as the Emergency Care Research Institute)). **NOTE:** *Recall Notices are only issued on a national basis.* Less critical product issues are addressed through direct communication from Designated Service Area Specialist (DSAS) to entities such as the Network Recall Coordinator (NRC), Facility Recall Coordinator (FRC) and/or Facility Designated Area Specialist (FDAS) with the Office of Product Recall (located in VHA Clinical Logistics Office (10F)) involvement as appropriate.

d. **Definitions.** The following definitions are applicable within this Directive:

(1) **Biologic (Human).** A biologic is a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from human tissue, or their products, and which is used medically as a diagnostic, preventive, or therapeutic agent. **NOTE:** *Blood and blood products are regulated as both drugs and human biologics.*

(2) **Durable Medical Equipment (DME).** DME includes items such as: oxygen concentrators, wheelchairs, hospital beds, home oxygen refills and liquid oxygen refills, and various other medical equipment and devices.

(3) **Health and Beauty Care.** Health and beauty care items include products to enhance beautification and complexion such as: lotions, creams, and body products that may be applied to the mouth, hair, face, or body (this includes cosmetics).

(4) **Human Transplant Tissue.** Human transplant tissue includes: skin, heart valves, pericardium, bone, connective tissue, cartilage, saphenous vein and other blood vessels, heterografts (e.g., bovine vascular and pericardial patches), and corneal transplants.

(5) **Medical Device.** A medical device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory that is intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease, injury, illness, or other condition; and is not a drug, human tissue, or used for sustenance.

(a) **Repairable Medical Devices.** Repairable medical devices are medical devices that can be repaired and returned to service.

(b) **Non-repairable Medical Devices.** Non-repairable medical devices include implants, catheters, and single-use devices.

(6) **Medical Product.** A medical product is any item other than a medical device that is used for diagnosis, treatment, or prevention of a disease, injury, illness, or other condition.

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(7) **Nutritional Supplements.** Nutritional supplements are any products (other than tobacco) that are intended to supplement the diet that bear or contain one or more of the following dietary ingredients: a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

(8) **Pharmaceuticals (Drugs).** Pharmaceuticals are any substances defined by the United States (U.S.) Food, Drug and Cosmetic Act, recognized under in the official U.S. Pharmacopoeia, and used in the diagnosis, treatment, or prevention of a disease, or as a component of a medication. *NOTE: Blood and blood products are regulated as both drugs and human biologics.*

(9) **Prosthetic and Orthotic Devices.** Prosthetic devices are surgical implants such as: pacemakers, hips and/or knees, stents, custom artificial limbs, and orthotic devices, such as leg braces.

(10) **FDA Class I Recall.** An FDA Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death.

(11) **VHA Hazard Recall Score.** The VHA Hazard Recall Score is a metric derived from the assessment of the detectability, probability, and severity of the potential injury resulting from the use of the defective medical device, medical product, drug, subsistence (food and food products), implantable device (including human tissue), or prosthetics; it is used to triage and identify the appropriate communication method (see Att. C).

(12) **Serious Illness or Injury.** A serious illness or injury is an illness or injury that is life threatening; or results in the permanent impairment of a body function or permanent damage to the body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(13) **Subsistence.** Subsistence is a food or food service product that provides necessary sustenance, nourishment, and support for daily dietary requirements for optimal health. About 90 percent of these products (twelve categories) are included in the VHA Subsistence Prime Vendor National Contract.

(14) **User Facility.** A user facility is a hospital, an ambulatory surgical facility, a nursing home, or an outpatient diagnostic or outpatient treatment facility which is not a physician's office.

3. POLICY: It is VHA policy that, effective November 1, 2004, recalls must be issued when an actual or potential threat to the life or health of VA patients is identified.

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4. ACTION

a. **Office of Product Recall (10F)**. Effective November 1, 2004, the Office of Product Recall (located in the VHA Clinical Logistics Office) is responsible for:

(1) Coordinating and monitoring the recall program as it is described in this Directive, and

(2) Disseminating recall information within VHA that are described in Recall Notices. Recall Notices must have a title, problem statement, background, action, completion date, point of contact, and, if appropriate, feedback and/or documentation requirements.

b. **Office of the Deputy Under Secretary for Health for Operations and Management (10N)**. Effective November 1, 2004, the Office of the Deputy Under Secretary for Health for Operations and Management is responsible for disseminating recall instructions that are contained within Patient Safety Alerts and Patient Safety Advisories. ***NOTE:** The appropriate NRCs, FRCs, FDASSs, and other parties needed to implement the recall must be identified in the Patient Safety Alert or Patient Safety Advisory.*

(1) Within VHA, a recall must be issued when a potential threat due to equipment design or product failure is detected that may cause serious adverse health consequences or death, temporary or medically reversible adverse health consequences, or when there is a probability of serious health consequences (see Att. A).

(2) A Recall Notice must be issued using the Recall Coordinator electronic mail group as described in the Recall Decision Tree (see Att. A).

c. **Designated Service Area Specialist (DSAS)**

(1) The following are the DSAS categories and the offices with technical responsibilities within the recall program (see Att. D):

(a) Biologics (Human), the contact office is Pathology and Laboratory Medicine Service.

(b) DME, Prosthetics and Orthotics, the contact office is Prosthetics and Sensory Aids Service.

(c) Health and Beauty Care, the contact offices are the Veterans Canteen Service and Pharmacy Benefit Management (PBM) Strategic Healthcare Group.

(d) Human Transplant Tissue, the contact office is Surgical Service.

(e) Non-repairable Medical Devices, the contact offices are Supply, Processing, and Distribution (SPD) and the Office of Patient Care Services.

(f) Nutritional Supplements, the contact offices are the PBM Strategic Healthcare Group, Nutrition and Food Service, Veterans Canteen Service, and the National Acquisition Center (NAC).

(g) Pharmaceuticals (drugs), the contact office is the PBM Strategic Healthcare Group.

(h) Repairable Medical Devices, the contact offices are the Center for Engineering and Occupational Safety and Health (CEOSH) and/or Biomedical Engineering Service, and the Office of Patient Care Services.

(i) Subsistence, the contact offices are Nutrition and Food Service, Veterans Canteen Service, and NAC.

(2) The DSAS is responsible for:

(a) Establishing a process, which is not dependent upon a single individual, to monitor external hazard and recall sources (such as FDA, manufacturers, JCAHO and ECRI) for potential recalls and advise the Office of Product Recall in the VHA Clinical Logistics Office (10F).

(b) Serving as the primary contact and investigator for all internally-identified hazards within their area of expertise and/or specialty.

d. **National Center for Patient Safety (NCPS) (10X).** Effective November 1, 2004, NCPS is responsible for:

(1) Utilizing the Patient Safety Information System and Root Cause Analysis reports to identify issues potentially requiring a recall.

(2) Working closely with other VHA program offices to develop and forward Patient Safety Alerts and Patient Safety Advisories that contain recall-related actions to the Office of the Deputy Under Secretary for Health for Operations and Management for distribution.

(3) Notifying the Office Product Recall (VHA Clinical Logistics Office (10F)) of issues potentially requiring recall that do not have a patient safety impact.

e. **National Acquisition Center (NAC).** Effective November 1, 2004, the NAC is responsible for:

(1) Serving as the primary contact point for all national contracts.

(2) Requiring all national contract vendors to notify the Contracting Officer of any recalls or important product safety issues.

(3) Ensuring that the Contracting Officer notifies the appropriate DSAS and the Office of Product Recall in the VHA Clinical Logistics Office (10F) for appropriate action.

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f. **Network Director.** Effective November 1, 2004, the Network Director is responsible for:

- (1) Ensuring that every VHA facility has identified a primary FRC and back-up FRC.
- (2) Designating a NRC (this will be the Network Chief Logistics Officer) and a back-up NRC Recall Coordinator.
- (3) Ensuring that Network-initiated contracts require vendors to notify the Contracting Officer of any recalls or important product safety issues.

g. **Network Recall Coordinator (NRC).** Effective November 1, 2004, the NRC is responsible for:

- (1) Working with the Network Patient Safety Officer on recall issues impacting patient safety.
- (2) Establishing and maintaining NRC electronic mail groups on Outlook.
- (3) Submitting the names of these mail groups to the Office of Product Recalls in the VHA Clinical Logistics Office (10F). These mail groups are as follows:
 - (a) NRC Group comprised of the NRCs and the back-up NRCs.
 - (b) FRC Group comprised of the FRCs and the back-up FRCs.
- (4) Ensuring every VHA facility has a documented program for responding to recalls that is fault tolerant and not dependent upon a single individual.
- (5) Reviewing and approving each VHA facility's plan for responding to recalls.
- (6) Conducting an annual review of each facility's recall program.
- (7) Reporting potential hazards identified by the medical centers, hospitals, and outpatient clinics to the appropriate VA Central Office contact or program office (see subpar. 4c(1)).

h. **Facility Director.** Effective November 1, 2004, the facility Director is responsible for:

- (1) Ensuring unsafe medical products are not used at their facility or in remote facilities under their jurisdiction.
- (2) Identifying a primary FRC and back-up FRC capabilities.
- (3) Designating FDAS, and alternate FDAS', or equivalent, for all categories identified in subparagraphs 4c(1)(a) through 4c(1)(j); these FDAS' are responsible for taking the actions required in the Recall Notice, Patient Safety Alert, or Patient Safety Advisory that designates recall actions.

(4) Developing a plan for addressing recalls. This plan must:

(a) Be designed to implement recalls received from VA Central Office as well as reporting locally-identified issues to VA Central Office.

(b) Address the review and action taken on recalls as they are received within the time period defined in the recall instructions. If parties other than those identified in the recall are impacted or are needed to successfully implement the recall, the FRC must ensure these additional parties are informed of their required responsibilities.

(c) Establish a method of providing feed back on all Class I recalls to the Office of Product Recalls in the VHA Clinical Logistics Office (10F) with the requested information, such as the number of items identified internally, time required to resolve, date of resolution, etc.

(d) Provide a system for maintaining records which detail the steps taken to resolve recalls, such as distribution lists, response times, number of items identified, final disposition of affected items and date resolved.

(e) Provide a system for monitoring FDA Enforcement Reports (available at web site: <http://www.fda.gov/opacom/Enforce.html>) and other sources, as available, for locally-affected products and devices.

(f) Establish a method of providing periodic reports to the Environment of Care Committee, or equivalent, documenting the facility's response to Patient Safety Alerts, Patient Safety Advisories, and Recalls.

(g) Define a mechanism for reporting internally-identified potential threats due to equipment design or product failure that may cause serious adverse health consequences or death, temporary or medically reversible adverse health consequences, to the Network Office for further investigation. This must be done as soon as possible and need not wait for final Root Cause Analysis results.

(5) Ensuring that facility-initiated contracts, or other locally purchased products, require vendors to notify the facility Contracting Officer of any recalls or important product safety issues.

(6) Submitting the plan to the Network for review and approval.

i. **Facility Contracting Officer.** Effective November 1, 2004, the facility Contracting Officer must notify the appropriate DSAS, the Office of Product Recall in the VHA Clinical Logistics Office (10F), and the facility Director of any recalls.

5. REFERENCES

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- a. Accreditation Manual for Healthcare Facilities, JCAHO.
- b. CFR 21, Volume 1, Chapter 1, Parts 7, 107, 806, and 1270.
- c. FDA Office of Regulatory Affairs' Office of Enforcement. Guidance For Industry: Product Recalls, Including Removals and Corrections. This can be found at web site: (http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm)

6. FOLLOW-UP RESPONSIBILITY: The VHA Clinical Logistics Office (10F) is responsible for the contents of this Directive. Questions may be addressed to 202-273-8014.

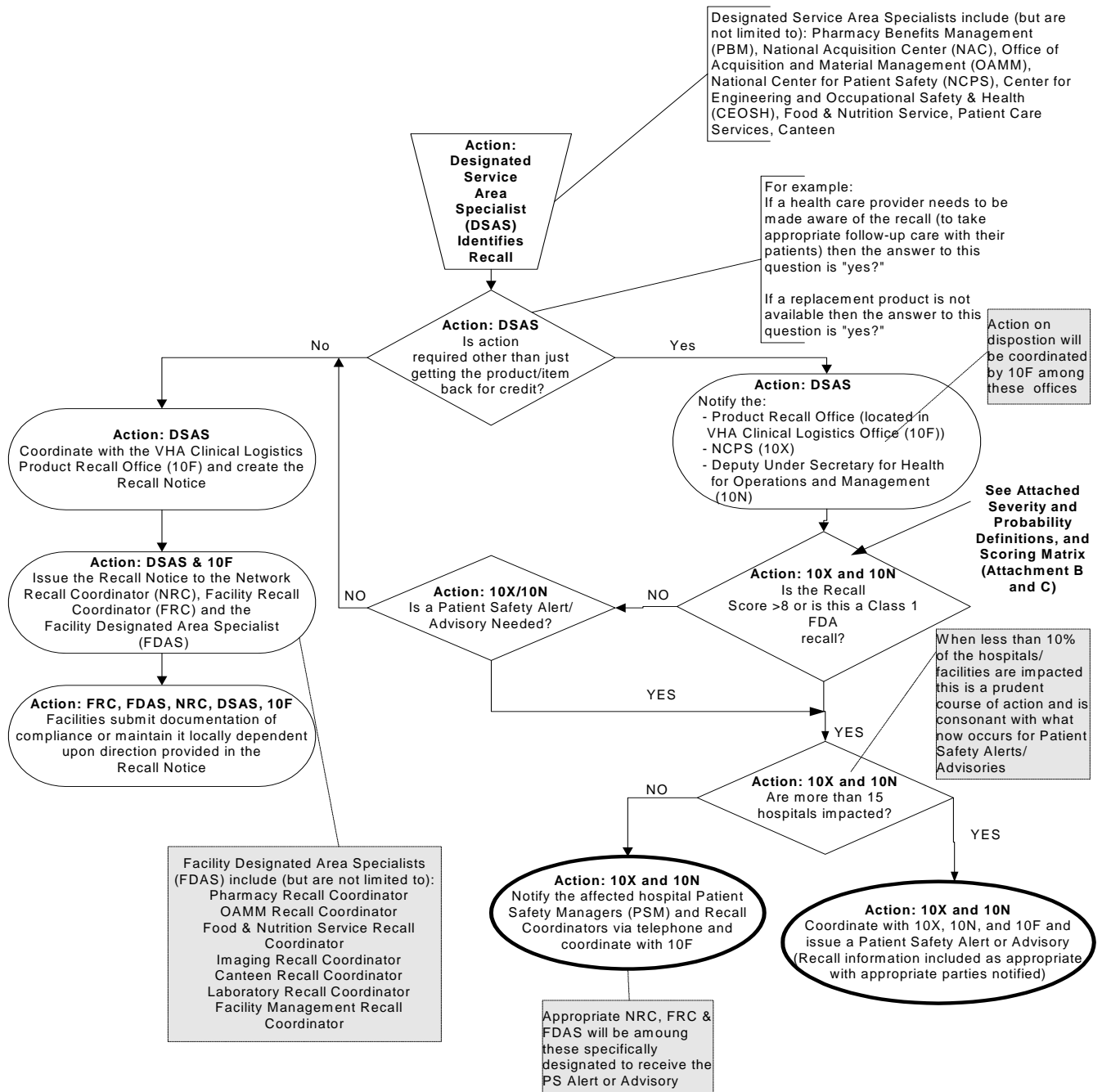
7. RESCISSIONS: None. This VHA Directive expires August 31, 2009.

S/ Jonathan B. Perlin, MD, PhD, MSHA, FACP
Acting Under Secretary for Health

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ATTACHMENT A

RECALL DECISION TREE

ATTACHMENT B

RECALL DIRECTIONS

1. Classify the Detectability Level using the definitions in Table 1.
2. Select the Severity Rating and Probability Rating using the definitions found in Tables 2 and 3.
3. Refer to the Recall Scoring Matrix (see Att. C); use the Scoring Matrix based upon the Detectability Level Rating from Step 1.
4. Determine the Recall Score using the Severity and Probability Ratings from Step 2.
5. When the Recall Score is known, use the Recall Decision Tree (see Att. A) to determine what action to take

Table 1: DETECTABILITY LEVEL RATING SCALE

| DESCRIPTION | DEFINITION |
|-------------|---|
| High | The defect is obvious or there is 100 percent automatic inspection with regular calibrations and standards and/or controls and failures, defects or vulnerability can be avoided. |
| Moderate | Some Statistical Process Control (SPC) is used during process or failure, defect or vulnerability is detectable immediately, prior to use. |
| Low | It is unlikely the end user will detect the defect prior to use. |

Table 2: SEVERITY RATING SCALE

| DESCRIPTION | DEFINITION |
|--------------|---|
| Catastrophic | Use of, or exposure to, the product will cause death, injury or illness that requires medical or surgical intervention to prevent permanent loss of function in sensory, motor, physiologic or intellectual skills to patient, visitor, employee, volunteer. |
| Major | Use of, or exposure to, the product can cause permanent lessening of bodily function (including, but not limited to: sensory, motor, physiological or intellectual) and disfigurement to patients, visitors, employees, and volunteers. |
| Moderate | Use of, or exposure to, the product can cause injury or illness that requires medical or surgical intervention, requiring increased length of care and loss time from work to patients, visitors, employees, and volunteers. |
| Minor | Use of, or exposure to, the product causes no injury or illness, and requires no medical or surgical intervention other than first aid treatment. Requires no increased length of care or loss time from work to patients, visitors, employees, and volunteers. |

Table 3: PROBABILITY RATING SCALE

| DESCRIPTION | DEFINITION |
|-------------|--|
| High | Likely to occur immediately or within a short period (may happen many times in 1 day). |
| Medium | Probably will occur (may happen several times in 1 week). |
| Remote | Unlikely to occur (may happen in 1 to 5 months). |

ATTACHMENT C

RECALL SCORING MATRIX

1. Select the appropriate Table (4A, 4B, or 4C) based upon the Detectability Level Classification (see Att. B).
2. Using the appropriate Table and the Severity and Probability ratings from Step 2 in Attachment B, determine the Recall Score.

Table 4A: Use This Table if the Detectability Level is **HIGH**

| Probability | Severity | | | | |
|-------------|----------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| | High | 12 | 9 | 6 | 3 |
| | Medium | 8 | 6 | 4 | 2 |
| | Remote | 4 | 3 | 2 | 1 |

Table 4B: Use This Table if the Detectability Level is **MODERATE**

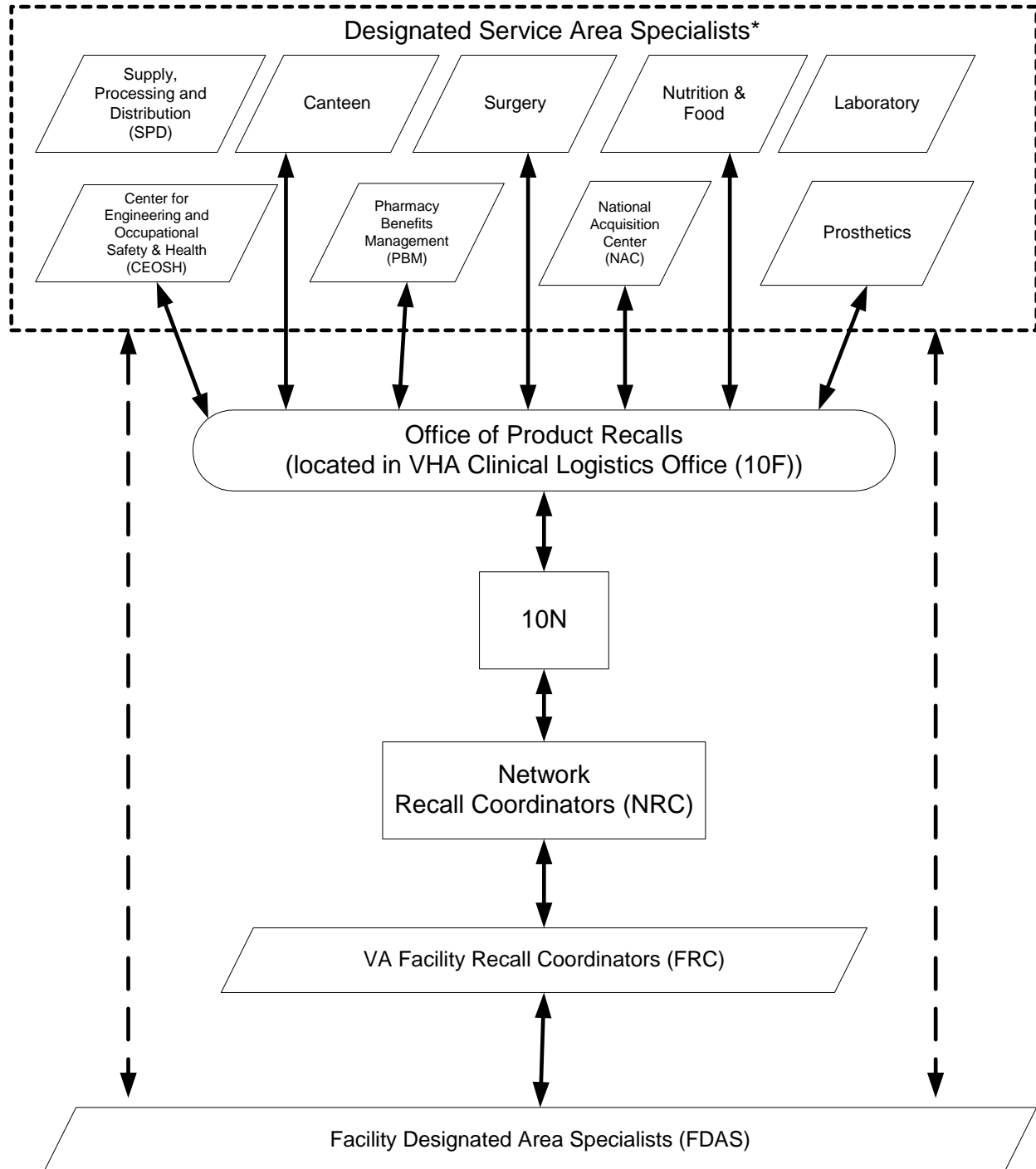
| Probability | Severity | | | | |
|-------------|----------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| | High | 24 | 18 | 12 | 6 |
| | Medium | 16 | 12 | 8 | 4 |
| | Remote | 8 | 6 | 4 | 2 |

Table 4C: Use This Table if the Detectability Level is **LOW**

| Probability | Severity | | | | |
|-------------|----------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| | High | 36 | 27 | 18 | 9 |
| | Medium | 24 | 18 | 12 | 6 |
| | Remote | 12 | 9 | 6 | 3 |

ATTACHMENT D

RECALL INFORMATION FLOW DIAGRAM



*Note: Designated Service Area Specialists may communicate independently with the Facility Designated Area Specialist based upon direction provided in the Recall Decision Tree (See Att. A).